REMARKS

Claims 1-12 are currently pending in the application. Claims 1 and 9 are in independent form.

The Office Action has set forth a requirement that additional sequences be included in the sequence listing. An amended sequence listing is provided herewith.

Claims 1-4 and 9 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a single purified alpha-N-Acetyl-D-galactosaminidase purified from *C.perfringens* comprising the partial amino acid sequences SEQ ID No: 1 and 8-16, does not reasonably provide enablement for any homologs or functional analogs of the same. The Office Action states that the claims are so broad as to encompass any sequence, including variants, mutants, and recombinants from any source having 70% amino acid identity over any functional portion of the enzyme. It is respectfully submitted that the specification discloses what is defined as an analog and homolog and provides adequate descriptions of such homologs, such that one of skill in the art could easily obtain homologs and analogs of the sequences recited in the claims. Specifically, additional sequences as disclosed on pages 7 and 8 of the specification as filed provide homologs of the partial sequence and as such, provide guidance as to what is intended to be included as a "homolog." Further, the claims have been amended to more specifically recite that the homologs must have at least 90% homology to the sequences recited in the claims. The techniques utilized to make modifications to the sequences, including insertions, substitutions, or deletions of a residue are well known to those of skill in the art. Therefore, one of skill in the art can substitute residues based on the disclosure provided in the specification as originally filed; and reconsideration of the rejection is respectfully requested.

Claims 1-4 and 9 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed

invention. It is respectfully submitted that the specification discloses what is defined as an analog and homolog and provides adequate descriptions of such homologs, such that one of skill in the art could easily obtain homologs and analogs of the sequences recited in the claims. Specifically, additional sequences as disclosed on pages 7 and 8 of the specification as filed provide homologs of the partial sequence and as such, provide guidance as to what is intended to be included as a "homolog." Further, the claims have been amended to more specifically recite that the homologs must have at least 90% homology to the sequences recited in the claims. The techniques utilized to make modifications to the sequences, including insertions, substitutions, or deletions of a residue are well known to those of skill in the art. Therefore, one of skill in the art can substitute residues based on the disclosure provided in the specification as originally filed; and reconsideration of the rejection is respectfully requested.

Claims 1-4 and 9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Levy et al article. Reconsideration of the rejection under 35 U.S.C. § 102(b) as being anticipated by the Levy et al article, as applied to the claims, is respectfully requested.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

The Office Action states that the Levy et al reference teaches an 8,000 fold purification of α-N-acetylgalactosaminidase from *Clostridium perfringen.* The Office Action concludes that since the term "sialidase" is known as the alternative name for "neuraminidase" it is clear that neuraminidase, as well as other impurities were removed from the α-N-acetylgalactosaminidase by the methods disclosed in the Levy et al reference. However, when read more specifically, the Levy et al reference teaches a method of purification that results in a preparation contaminated with multiple species of enzyme.

In the Levy et al article, it is postulated that the α-N-acetylgalactosaminidase is a multi-enzyme complex that needs to be dissociated. In the final "dissociated" preparation they measure 0.1%, 1.9%, and 1.2% contamination with neuraminidase, ß-galactosidase, and ß-N-acetylglucosaminidase, respectively. Furthermore, in the SD-PAGE of their preparation, there is revealed multiple bands of α-N-acetylgalactosaminidase activity along with several other protein bands. This is in contradistinction with the purified enzyme of the presently pending independent claims, wherein only one band is found on the SDS-Page of the final enzyme. This band is α-N-acetylgalactosaminidase. Further, there is no detectable ß-galactosidase or ß-N-acetylglucosaminidase activity.

In direct comparison, the presently pending independent claims claim an enzyme that contains therein less than 0.8 ng of neuraminidase as detected per milligram of pure α-N-acetylgalactosaminidase. In comparison, the enzyme conglomeration of the Levy et al article contains approximately 62 ng of neuraminidase. Accordingly, the enzyme of the presently pending independent claims has at least 77-fold greater neuraminidase removal than that of the Levy et al article.

Further, the Levy et al. data is converted from μmoles of substrate dehydrolyzed per hour to μmoles hydrolyzed per minute. The Levy et al preparations have a specific activity of 17.4 compared to the present mean activity of 42.4 for the enzyme of the presently pending independent claims. Given its explicit teaching there is no disclosure of the enzyme recited in the presently pending independent claims. Since, the Levy et al article does not disclose the enzyme recited in the presently pending independent claims, reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above. The prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is

respectfully submitted that all of the pending claims are patentable over the prior art.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, PLLC

Amy E. Rinaldo
Registration No. 45,791
30500 Northwestern Highway
Suite 410
Farmington Hills, Michigan 48334
(248) 539-5050

Dated: July 19, 2004

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

Express Mail Mailing Label No.: EV 442292243 US
Date of Deposit: July 19, 2004

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office To Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop: Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Connie Herty